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UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,276	06/27/2001	David Rollo	ADAC19012	5224

7590   12/03/2004

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EXAMINER
JUNG, WILLIAM C

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

DEC 2 7 2004

TECHNOLOGY CENTER R3700

	Application No.	Applicant(s)
Office Action Summary	09/894,276	ROLLO ET AL.
	Examiner	**Art Unit**	
	William Jung	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 27, 2001* .

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

        1.☐ Certified copies of the priority documents have been received.

        2.☐ Certified copies of the priority documents have been received in Application No. _____ .

        3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)   4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)   5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .   6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2.   Claim 1 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by *Logan et al*

(US 4,873,632).

Claim 1: Logan et al anticipate all claimed invention in claim 1. Logan et al disclose of

nuclear or gamma camera system where the pixel data or numerical values of the image are

processed and store according to photopeaks in multiple energy windows with scatter corrector

to correct or reduce scatter by combining the counts of the multiple windows. The scatter

corrector or reducer is coupled to the image processor and image data storage (col. 3, lines 3-15;

col. 5, lines 21-48; col. 5, lines 52-58).

Claims 8-12: Logan et al further disclose that the scatter correction algorithm includes

mathematically combining by either additive or subtractive process (col. 10, line 67 – col. 11,

line 34; col. 11, line 61 – col. 12, line 11) . Further more, the scatter corrector acts to correct the

scatter on a pixel-by-pixel basis with typical X,Y coordinates of the two-dimensional image .

The photopeak energy windows (bell curve) may overlap depending on the emission energy of

the radionuclides.

Claim Rejections - 35 USC § 103

3.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

4.   Claims 2, 3, and 5 are under 35 U.S.C. 103(a) as being unpatentable over *Logan et al*.

Claims 2 and 3: Logan et al disclose that the gamma camera detector detects multiple

photopeaks, whether the radionuclides emits single or dual energy, the detection allows dual

energy source. Therefore, Logan et al's gamma camera renders obviousness to utilize two

different radiation sources or radioactive carrier to detect the photopeaks (col. 5, lines 33-38).

Logan et al further disclose that the background scatter of the radionuclides is lower than the

high energy level main photopeaks (col. 5, lines 58-66).

Claim 5: Logan et al disclose of prior art where the nuclear or gamma camera is utilized

with Thallium (Tl), Gallium. Indium, and technetium (Tc)(col. 1, lines 23-44).

5.   Claims 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Logan

et al* as applied to claim1-3 above, and further in view of *Chilton et al* (US 7,706,683).

Logan et al substantially disclose of all claimed invention in claims 4, 6, and 7.

However, Logan et al do not disclose of the apparatus described above is applied in lung

perfusion or stress analysis with Tc and Xe. Chilton et al further teaches that the Xe is an

alternative radionuclides source that can be detected by the nuclear or gamma camera as

described by Logan et al. Furthermore, Chilton et al teach that the radioactive gas, Xe, inhaled

by a patient, fills the lung. The radioactivity of the Xe gas is detected with radioactive or nuclear

camera for diagnostic procedure. The diagnostic information includes distribution of the gas in

the lung (perfusion) (col. 1, lines 19-27) and the lung distress (or stress) (col. 3, lines 16-34).

Therefore, it would have been obvious to one having an ordinary skill in the art at the time the

invention was made to apply teachings of Chilton et al's application of Xe in lung perfusion and

stress study/analysis with the nuclear or gamma camera apparatus described by Logan et al.

6.   Claim 13-15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Flanagan et al (US 5,093,105) in view of *Logan et al.*

Claims 13, 15, 18, and 19: Flanagan et al substantially disclose of all claimed invention in

claims 13, 15, 18, and 19. Flanagan et al disclose of lung perfusion study/imaging by

introducing radiotracers into patient via inhalation where the radiotracers emit gamma radiation

such as Tc-99m, ^{201}Tl, and ^{123}I (col. 1, lines 57-61; col. 2, lines 7-24). However, Flanagan et al

lacks two distinct radioactive carrier introduced to the patient. Logan et al teaches that the

gamma camera detector detects multiple photopeaks, whether the radionuclide emits single or

dual energy, the detection allows dual energy source detection simultaneously. Therefore, Logan

et al's gamma camera renders obviousness to utilize two different radiation source or radioactive

carrier to detect the photopeaks simultaneously. Therefore, it would have been obvious to one

having an ordinary skill in the art at the time the invention was made to apply the teachings of

Logan et al to improve the deficiency in the teachings of Flanagan et al.

Claims 14: Flanagan et al also disclose that the Tc-99m or 99mTc ligand is a

macroaggrecated albumin (MAA) (col. 4, lines 31-35).

7.   Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Flanagan et al and *Logan et al* as applied to claim13 above, and further in view of *Chilton et al*

(US 4,706,683).

Flanagan et al and Logan et al substantially disclose of all claimed invention in claims 16

and 17. Although Flanagan et al and Logan et al do not include gaseous radiotracer such as

Xenon, Chilton et al teach of such improvement. Chilton et al disclose that the Xenon gas is

administered to a patient by inhalation for lung perfusion study Col. 1, lines 19-27; col. 3, lines

16-42). Therefore, it would have been obvious to one having an ordinary skill in the art at the

time the invention was made to apply the teachings of Chilton et al's Xenon gas administration

to the teachings of Flanagan et al and Logan et al's lung perfusion imaging method to achieve

the claimed invention.

Conclusion

8.   The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure.

Madden et al (US 5,694,933), *Madden et al* (US 6,135,955), *Layne et al* (US 4,094,965), and

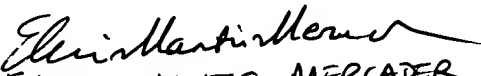*Logan et al* (IEEE Transactions on Medical Imaging).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to William Jung whose telephone number is 703-605-4364. The

examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Denis Ruhl can be reached on 703-305-3256. The fax phone number for the

organization where this application or proceeding is assigned is 703-308-0758.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is 703-308-1148.

WCJ
November 18, 2003

ELENI MANTIS MERCADER
PRIMARY EXAMINER
ART UNIT 3737

		Application/Control No.	Applicant(s)/Patent Under Reexamination
Notice of References Cited		09/894,276	ROLLO ET AL.
		Examiner	Art Unit	Page 1 of 1
		William Jung	3737	

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-4,873,632	10-1989	Logan et al.	250/363.02
	B	US-5,093,105	03-1992	Flanagan et al.	424/1.13
	C	US-4,706,683	11-1987	Chilton et al.	600/431
	D	US-5,694,933	12-1997	Madden et al.	600/431
	E	US-6,135,955	10-2000	Madden et al.	600/436
	F	US-4,094,965	06-1978	Layne et al.	424/1.37
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	W. Logan and W.D. McFarland, "Single Photon Scatter Compensation By Photopeak Energy Distribution Analysis", IEEE Transactions on Medical Imaging, Vol. 11, pps. 161-164, June 1992
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Single Photon Scatter Compensation by Photopeak Energy Distribution Analysis

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Abstract

Scattered photons degrade nuclear medicine image contrast and resolution, and preclude simple attenuation corrections. Current scatter corrections utilize events with energies below PHA window levels, making attenuation corrections depth and source distribution dependent. This new scatter rejection technique analyzes only the photon signals occurring within the range of standard PHA windows. In real time, at each image location the PHA window energy distribution is analyzed, a scatter fraction determined, and a scatter corrected number of events are output. The method can be adapted to any imaging system which produces event location and energy signals. Attenuation corrections (u=0.15, 140 keV) are within 6% for 2 to 10 cm depths.

I. INTRODUCTION

. All nuclear medicine imaging systems utilize energy selective detection to limit the number of scattered photons collected, since erroneous source position data is introduced when scatter photons are detected and used in generating images. Due to the relatively poor energy resolution of currently available scintillation detectors, a significant fraction of detected events accepted by the energy selective pulse height analyzer windows (PHAW) are actually scattered photons. Methods have been introduced to measure intensity of scatter photons [1,2], and subsequently make corrections in the data used to generate images. These generally involve measuring the intensities of scattered photons using a "scatter window" PHAW, or a range of energies, below the photopeak PHAW energy region. Since there is an angle-energy relationship for Compton scattered photons, source locations from which photons originate and then scatter with resulting energies below the photopeak PHAW are generally different than those source locations that emit the photons which scatter but are accepted by the photopeak PHAW. This is illustrated in Figure 1, where relative to scattering at point P, the photopeak PHAW accepts photons scattered within the angular range $\pm \theta_w$, while photons of lower energies (below the photopeak range) can originate only from locations within the angular range indicated by $\pm \theta_s$. Source intensities vary with location, and therefore generat-

ing scatter corrections based on scatter photon intensities with energies below the photopeak region can introduce erroneous image data. This erroneous image data could be avoided if corrections were based only on detected events with energies in the photopeak PHAW range.
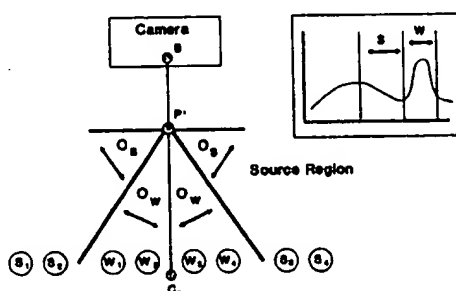
Sources W_1 - W_4 scatter into window W
Sources S_1 - S_4 scatter into window S

Figure 1. Gometric relationship between scatter source location and energy range of pulse height analyzer window.

II. DESCRIPTION OF METHODS

We have been working on methods for scatter correction which utilize only the photons detected with energies within the photopeak PHAW, i.e. only those detected photon events which are accepted and included in conventional setting of PHA windows. This is a task of separating the non-scattered photon intensities from scattered photon intensities which occur with overlapping energy spectra in the photopeak PHAW. When accomplished, this will avoid additional erroneous image data from corrections made using scatter photon intensities at energies below the PHAW region. Figure 2. illustrates both the basic scatter problem, and also the general features of scatter and non-scatter energy spectra within the photopeak PHA region, which are important for this new scatter correction technique. Data was collected from a point source of 140 kev photons in air, and at the same source/detector positions in water. The calculated in-water curve is lower than the measured curve due to detected scatter photons with pulse

heights which fall within the photopeak PHAW. The difference between the calculated and measured energy (pulse height) curves is the scatter energy spectrum. For the source in water, the true non-scatter photon energy spectrum is the same symmetric peak as the in-air measured spectrum, but reduced in intensity by attenuation.
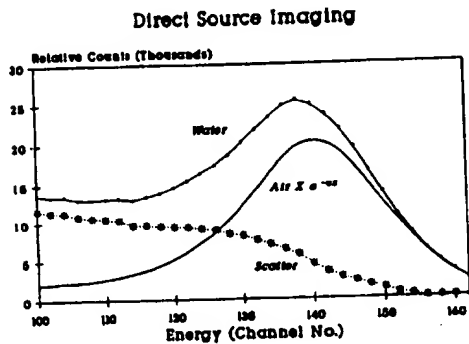
Direct Source Imaging

Figure 2. Point source energy spectra in air and water. Air spectrum multiplied by good geometry attenuation factor for water. Difference in measured water spectra and calculated attenuation of air data is scatter reaching detector.

The scatter spectrum for the same energy range is very asymmetric. Several measurements were made with 140 kev point sources in air and water, and the resulting scatter photon energy spectra were obtained in the region of the photopeak as shown in Figure 3. These measurements show that the shape of the scatter photon energy spectrum from a point source is nearly the same for depths of 2 to 10 cm in water. Since the shape of the scatter energy spectra is essentially depth independent in the region of the photopeak, the PHAW can be divided into two regions such that each region will contain approximately equal numbers of detected scatter photon events, regardless of source depth (location). This division of the photopeak energy region scatter spectra into two equal regions is indicated by vertical line C in Figure 3. The use of equal scatter division of the PHAW into two regions for point by point scatter correction (or scatter rejection) is illustrated in Figure 4. The equal scatter division line divides the PHAW in to two regions labeled A and C. For each point in the image field, the number of events occurring in region C is subtracted from the number of events occurring in region A. Since the number of scatter events in the two regions is the same, the difference A - C contains no scatter. Region C is considerably narrower than region A,

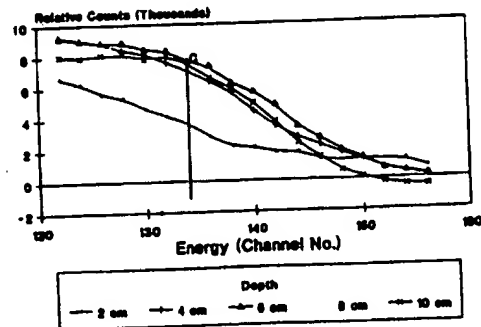so that most of the photopeak non-scatter events occur in region A.

Figure 3. Measured scatter energy spectra in region of photopeak for 140 keV photons emitted by point source in water.
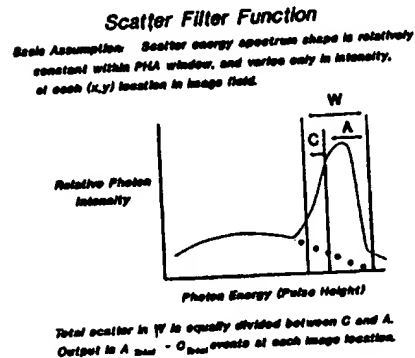

Figure 4. Scatter filter function based on dividing photopeak PHAW asymmetrically into two regions of equal scatter intensity.

III. HARDWARE IMPLEMENTATION

This scatter rejection method has been incorporated into an electronic system [3] which implements the A - C subtraction in real-time for a matrix of points covering the field of view for a conventional 15 inch gamma camera. This system reads the camera X and Y position signals, the camera unblank line and the energy signal. The scatter rejection circuitry keeps a running account of A - C at every image field location (currently 256 by 256 matrix), and updates for each detected event. If the running total is positive, then the event is accepted for the image. If the running total is negative, the event is rejected. The scatter

rejection circuitry operates at speeds faster than the camera, so that no deadtime or lose of counts occurs. The X and Y position signals, and the unblank pulse produced by the scatter rejection system are identical to those produced by the camera, so that the scatter rejection system can be interposed between the
camera and any device that normal'v receives the camera output signals.

There is a calibration routine to determine the sizes of the A and C regions for each camera. This is currently done manually in the prototype system, however it can easily be automated for routine use.

IV. EXPERIMENTAL MEASUREMENTS

A series of camera images of two small (5 cc volume) sources were obtained with, and without, the scatter rejection circuitry. The sources were positioned about 2 cm apart, and the pair of sources was imaged over a range of distances from the camera face in air, and in water. The two sources were clearly resolved at the greatest distance from the camera in air, and with scatter rejection; however without the scatter rejection, there was significant over lapping of the scatter fields from one source to the other for the images in water. The Tc-99m activities of the sources were selected so that one was approximately ten times the other. Measured counts were obtained from computer collected images using the same region of interest for sets of images obtained at the same depth with and without the scatter rejection circuitry. Appropriate time corrections for made for decay over the sequence of imaging. Figure 5 compares the counts obtained from these two sources in air and water. Ratios of counts measured from the sources at various depths, and comparison of in-water source counts to calculated attenuation of measured in-air counts are given. The accuracy of scatter rejection imaging compared to attenuation calculations with in-air measurements is better than 6% out to depths of 10 cm.

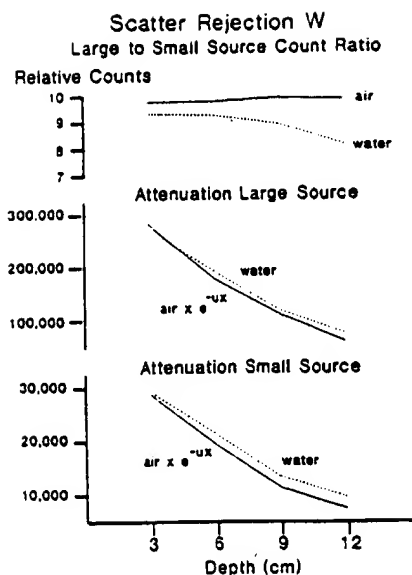**Scatter Rejection W**
Large to Small Source Count Ratio

Figure 5. Relative count ratios, and calculated and measured attenuation for two adjacent sources in water. Source activities were approximately 10 to 1.

The scatter rejection method has also been used for imaging of several phantoms and patient studies. Figure 6 is a set of images obtained from an anterior Tc-99m sulfur colloid liver/spleen procedure. The upper two images are from a standard PHAW; the lower two images used the A - C scatter rejection technique. In both cases, the image on the right is thresholded to visualize relatively low level count densities. Note that in the normal PHAW thresholded image (Fig. 6, upper right), the scatter from the liver and spleen activities "blossoms" out over adjacent marrow activity in ribs and spine. In the thresholded scatter rejection image (Fig. 6 lower right), the scatter from the liver and spleen has largely been eliminated, and the low level marrow activity in ribs and central axis can be visualized immediately adjacent to the high activity margins of the liver and spleen.

V. DISCUSSION AND CONCLUSIONS

The importance of scatter correction, or as in this case, scatter rejection, is more than just clarity or contrast in standard planar imaging. Quantitative parameters including accurate attenuation correction are highly sensitive to scatter, particularly in tomographic emission imaging. Limitations of earlier methods to used measured scatter photon intensity for corrections may be related to the geometry of source locations and scattered photon energy. The scatter window technique has been shown to be source geometry dependent [4], with variable window factors
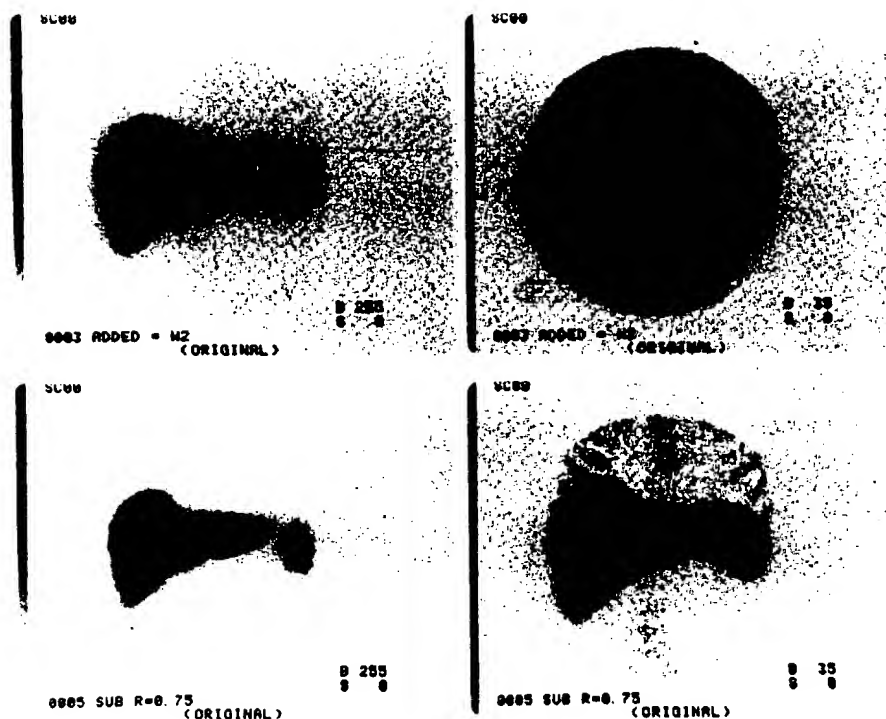
Figure 6. Tc-99m sulfur colloid liver/spleen images with, and without scatter rejection. Images on right are thresholded to display low level count densities.

needed and only regional accuracy. Energy weighted acquisition and associated spatial filters also has been shown to be object dependent, with variation of approximately 30% in apparent source intensity for 10 cm depth range [5]. In contrast, the results with scatter rejection based only on photon intensities within the PHAW energy region appear to be relatively object independent, and for imaging of the high/low activity source pair, an accuracy of about 6% was observed to depths of 10 cm in water.

Scatter photons have an intrinsic uncertainty about the source location because Compton scattering occurs with equal probability of orientation around the primary photon path direction (variation in azimuth angle). Therefore, scatter photons are essentially a noise factor in the image, while detected non-scatter photons represent image signal. In the scatter rejection method described above, the A - C operation eliminates most of the noise factor, but lowers

signal as well, since some of the detected events in region C are non-scatter photons. For the cameras used in the design and development of the system, the lose of non-scatter photons from region A has been about 20%. Since the signal to noise ratio (scatter noise) is substantially improved, and the 20% reduction in true counts will generally be statistically acceptable.

This approach to scatter rejection is not limited to standard gamma cameras, or single photon emitting radionuclides. The method can be applied to any imaging system that uses one or more photopeak PHAWs for general scatter rejection, including PET imaging systems.

VI. REFERENCES

1. R.J. Jaszczak, K.L. Greer, C.E. Floyd, Jr., C.C. Harris, and R.E. Coleman, "Improved SPECT quantification

using compensation for scatter photons," *J Nucl Med*, vol. 25, pp. 893-900, 1984.

2. J.J. Hamill and R.P. DeVito, "Scatter reduction with energy weighted acquisition," *IEEE Trans Nucl Sci*, vol. 36, pp. 1334-1339, 1989.

3. K.W. Logan and W.D. McFarland, "Apparatus and methods for scatter reduction in radiation imaging," *U.S. Patent No. 4,873,632*, October 10, 1989.

4. K.F. Koral, F.M. Swailem, S. Buchbinder, N.H. Clinthorne, W.L. Rogers, and B.M.W. Tsui, "SPECT Dual-energy-window Compton correction: Scatter multiplier required for quantification," *J Nucl Med*, vol. 31, pp. 90-98, 1990.

5. R. P. DeVito, J.J. Hamill, J.D. Treffert, and Everett W. Stoub, "Energy-weighted acquisition of scintigraphic images using finite spatial filters," *J Nucl Med*, vol. 30, pp. 2029-2035, 1989.